

MECHANICAL FAILURE
of
TOTAL HIP REPLACEMENT

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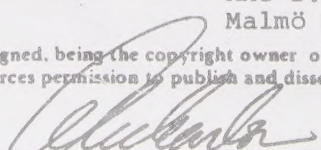


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Title and subtitle Mechanical failure of total hip replacement.			
Abstract On the basis of about 380 total hip replacements, the rate of loosening of the stem prosthesis, the symptoms of loosening, the rate of fracture of the metallic stem and the outcome of revision in cases of non-infectious stem loosening were studied. An attempt was also made to evaluate factors causing loosening, including the pre-operative quality of the bone. The following conclusions could be drawn: 1. Loosening of the stem prosthesis - a radiolucent zone - was observed in 36 per cent. 2. Loosening was most commonly observed during the first post-operative years; a steady state was reached after 5 - 6 years. 3. The radiolucent zone - the loosening - preceded the pain which was present in about 25 per cent of the cases. Moreover, with increasing width of the radiolucent zone, the fraction of painful hips increased. In hips with a zone of 4 mm or more, 50 per cent were painful. 4. Defects in the cement support were found to promote loosening whereas varus malposition, although common in loosened hips requiring revision could not be demonstrated to contribute significantly. 5. Male sex, previous hip surgery and, in women, young age, were correlated to loosening whereas diagnosis, body weight and, in men, age, was not. With respect to stem fracture, heavy male patients with bilateral THR make a risk group. 6. Loosening was not correlated with the pre-operative bone quality. 7. The frequency of stem-fracture was about 0.7 per cent. 8. Three per cent of all non-infected hips and 8 per cent of the loosened stems required revision which in most cases relieved the pain and resulted in a good walking capacity and range of motion.			
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PAPER I

351 TOTAL HIP REPLACEMENTS ACCORDING TO CHARNLEY

A review of complications and functional results.

by

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Total hip replacement is a well documented and widespread procedure, the number of which performed each year still seems to increase. In 1979, approximately 4,000 hips were replaced in Sweden with a population of about 8 millions.

The aim of this study was to present the function and the complications in a material which had undergone a comparatively long observation.

The included hips constitute the base material of previously published investigations concerning postoperative dislocation (Carlsson and Gentz 1977), peroperative bleeding (Carlsson et al. 1977b) and mechanical loosening of the stem prostheses (Carlsson and Gentz 1980). These hips also form part of a larger group of patients in whom deep infection has been investigated.

PATIENTS AND METHODS

Between 1968 and 1972, 351 total hip replacements were performed in 310 patients in the Department of Orthopedic Surgery at Malmö General Hospital. The annual number of operations during the above-mentioned period and the following years is presented in Figure I:1. The hips were operated upon by 18 more or less experienced surgeons according to Charnley's original technique and approach.

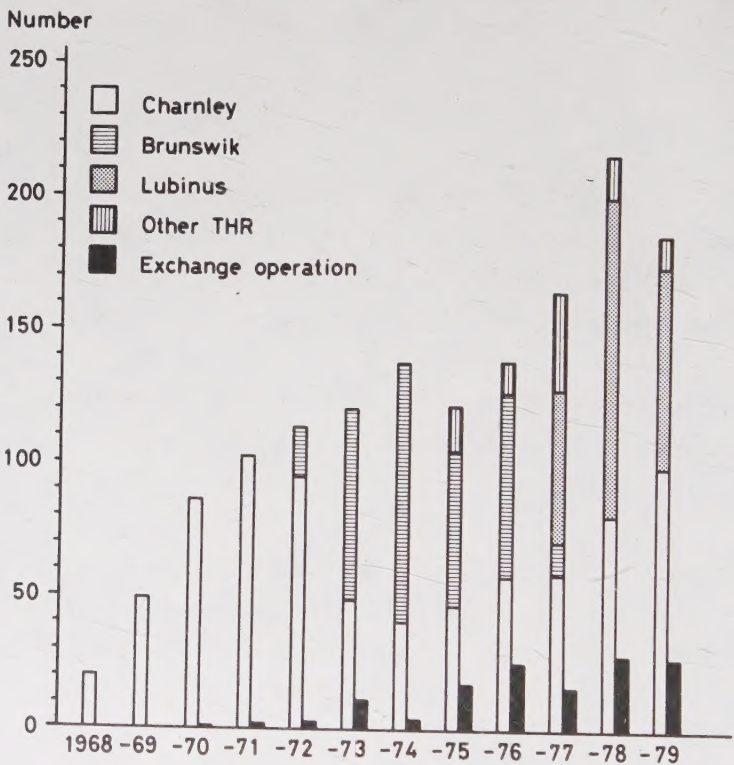


Figure I:1. The annual number of THR performed at Malmö General Hospital.

All surviving patients were re-examined by the author during the years 1973 - 1974, and a second time in 1976 - 1977. In the presentation of deep infection and mechanical loosening of the stem prostheses nine hips were excluded from the base material, six because the patients died within one year post-operatively (all within six months) and three because of insufficient radiographic information. Thus, 342 hips in 303 patients remained.

In the presentation of function only hips re-examined twice clinically and radiographically are included. Patients were lost by re-operations and by deaths. The interval between the operation and the first re-examination averaged 36 ± 14 months, and between the operation and the second re-examination 72 ± 15 months. There was no difference in the time of observation between category A, B and C patients (see below).

The numerical system of grading the hip function, originally Revised by Merle d'Aubigné and Postel and modified by Charnley, was used (Merle d'Aubigné and Postel 1954, Charnley 1972 and 1979) (Table I:1).

By adding prefixes A, B and C to the numerical grading the patients can be grouped into categories (Charnley 1972 and 1979). A category A patient is physically fit in all respects relating to function and without any defect other than the hip affected. Category B patients have both hips affected but are otherwise physically fit. Patients with both hips replaced by a total hip at the time of re-examination were categorized as BB (Charnley 1979). Category C was reserved for patients with conditions directly impairing the act of walking such as cardiac insufficiency, gonarthrosis or rheumatoid arthritis. The distribution between groups A, B and C is shown in Table I:7.

Previous hip surgery

Seventy of the 342 hips had previously been operated upon with the following methods; osteotomy 21, hemi-arthroplasty 6,

Table I:1. Method of grading functional status of the hip (Merle d'Aubigné and Postel, modified by Charnley).

GRADE	1	2	3	4	5	6
PAIN	Severe Spontaneous	Severe on attempting to walk. Prevents all activity	Pain tolerable permitting limited activity	Pain only after some activity; disappears quickly with rest	Slight or intermittent pain on starting to walk but getting less with normal activity	No pain
WALK	Bedridden or few yards; two sticks or crutches	Time and distance very limited with or without sticks	Limited with one stick (less than one hour). Difficult without stick. Able to stand long periods	Long distance with one stick; a limited without a stick	No stick but Normal	Normal
RANGE OF MOTION	Passive range: sum of flexion, rotation, abduction - adduction.					
	0 - 30	31 - 60	61 - 100	101 - 160	161 - 210	211 - 260

nailing because of femoral neck fracture 20, arthrodesis 5, mold arthroplasty 7 and various other methods 11.

RESULTS

Sex, age and diagnosis

Sex, age and diagnosis are presented in Table I:2. The female/male ratio was 1.5:1. Patients operated upon for rheumatoid arthritis and fracture complications were significantly younger than patients with primary osteoarthritis ($p < 0.001$). The men were significantly younger than the women at the time of the operation ($p < 0.05$).

Deep infection

The diagnosis of deep infection in 54 cases was based on the presence of an abscess or a sinus - 34 cases - and pain and elevated ESR in 20 cases. During the period covered by this investigation antibiotic prophylaxis was introduced. This was followed by a significant reduction in the number of deep infections (Carlsson et al. 1977a).

The rate of deep infection varied significantly ($p < 0.01$) depending on the surgeon (Table I:3). This could not be explained by one surgeon operating upon technically more difficult hips than other surgeons since the differences remained after exclusion of hips with conditions other than primary osteoarthritis without previous surgery. Nor did experience reduce the rate of infection.

No preoperative diagnosis was over-represented among infected hips. The rate was 17 per cent in primary osteoarthritis as compared to 13 per cent in rheumatoid arthritis (Table I:4). There was no tendency towards higher rate of deep infection in previously operated hips in either group.

No attempt was made to analyze superficial infections.

Table I:2. Sex, age and diagnosis.

	Primary osteoarthritis	Rheumatoid disease	Fracture complications	Various	Total
Men	65.9 $\pm$ 6.7 n = 114	58.6 $\pm$ 6.7 n = 13	54.8 $\pm$ 17.5 n = 9	61.2 $\pm$ 15.3 n = 4	64.3 $\pm$ 8.5 n = 140
Women	68.6 $\pm$ 7.6 n = 147	61.0 $\pm$ 9.7 n = 29	58.9 $\pm$ 11.5 n = 18	63.3 $\pm$ 11.9 n = 17	66.3 $\pm$ 9.3 n = 211
Total	67.4 $\pm$ 7.3 n = 261	60.3 $\pm$ 8.2 n = 42	57.5 $\pm$ 13.8 n = 27	62.9 $\pm$ 12.3 n = 21	65.5 $\pm$ 9.0 n = 351

Table I:3. Deep infection correlated to surgeon. M represents 13 surgeons with 1 - 12 operations each.

Surgeon	No. of hips	No. infected	Per cent infections	Per cent infected. Only primary osteoarthrosis without previous hip surgery
A	80	24	30%	22%
B	61	4	7%	3%
C	57	5	9%	12%
D	55	9	16%	19%
E	22	2	9%	13%
M	67	10	15%	16%
Total	342	54	16%	14%

Table I:4. Preoperative diagnosis in infected and non-infected hips.

	Primary osteoarthritits	Rheumatoid disease	Fracture complications	Various	Total
Non-infected hips	212	35	24	17	288
Deep infection	43	5	2	4	54
Total	255	40	26	21	342

Other complications

Other complications are presented in Table I:5. There was no peroperative mortality except for one man who died after 6 weeks because of pulmonary embolism.

The thromboembolic complications were suspected on clinical

grounds and 20 of the deep vein thromboses were verified by venography. The 17 postoperative dislocations have been discussed in a previous paper (Carlsson and Gentz 1977).

Mechanical loosening of the femoral head prosthesis, defined as a radiolucent zone developing between the cement and the metallic shaft proximally and laterally, was observed in 36 per cent of 288 non-infected hips. For a detailed analysis, the reader is referred to a previous paper (Carlsson and Gentz 1980).

Non-infectious loosening of the acetabular prostheses occurred in 3/288 hips (1 per cent). One was a woman suffering from primary coxarthrosis. In two patients with rheumatoid arthritis the sockets migrated centrally into the pelvis.

Table I:5. Systemic and early local complications.

Pulmonary embolus (one fatal incl.)	6
Deep vein thrombosis	29
Pneumonia	12
Cardiac complications	9
Cerebral ischaemia	5
Gastric bleeding	4
Urinary tract infection	65
Permanent peroneal paralysis	1
Transient peroneal paralysis	6
Femoral nerve injury	1
Perforation of the femoral shaft	4
Postoperative dislocation	17
Miscellaneous	5

Function

Patients with deep infection are excluded when analyzing function. All other patients are included provided they have been re-examined twice. With regard to pain and range of motion patient category A, B and C are grouped together since the differences were negligible. The average *pain* score was the same at the first and the second re-examination (Figure I:2). The score for *range of motion* was slightly increased at the second re-examination (Figure I:2). The average score for *function of walking* was 5.0 in category A patients and the slight decrease at the second follow-up was non-significant (Figure I:2, Table I:6). The average score was lower - 4.5 - in category B patients, the same on both occasions. The average score was lowest in category C patients - 3.7 and 3.2, respectively - without any significant difference between the two re-examinations (Table I:6). All 13 category BB patients were pain-free and as demonstrated in Table I:7, the function of walking was satisfactory.

Table I:6. Function of walking in non-infected category A, B and C hips at the first and second re-examination. Group B includes BB.

		No. of hips	1	2	3	4	5	6	Average
29%	A 1	69		4	6	14	7	38	5.0
	A 2	69		7	6	15	7	34	4.8
33%	B 1	79		6	12	24	14	24	4.5
	B 2	79		9	12	22	5	31	4.5
38%	C 1	89		22	23	22	5	17	3.7
	C 2	89	7	28	22	13	5	14	3.2

The patients' opinion

Deep infection is always a failure and therefore only non-infected hips are considered under this headline. The patients were asked to render their opinion regarding hip function in terms of asymptomatic, better, unimproved or worse. At the

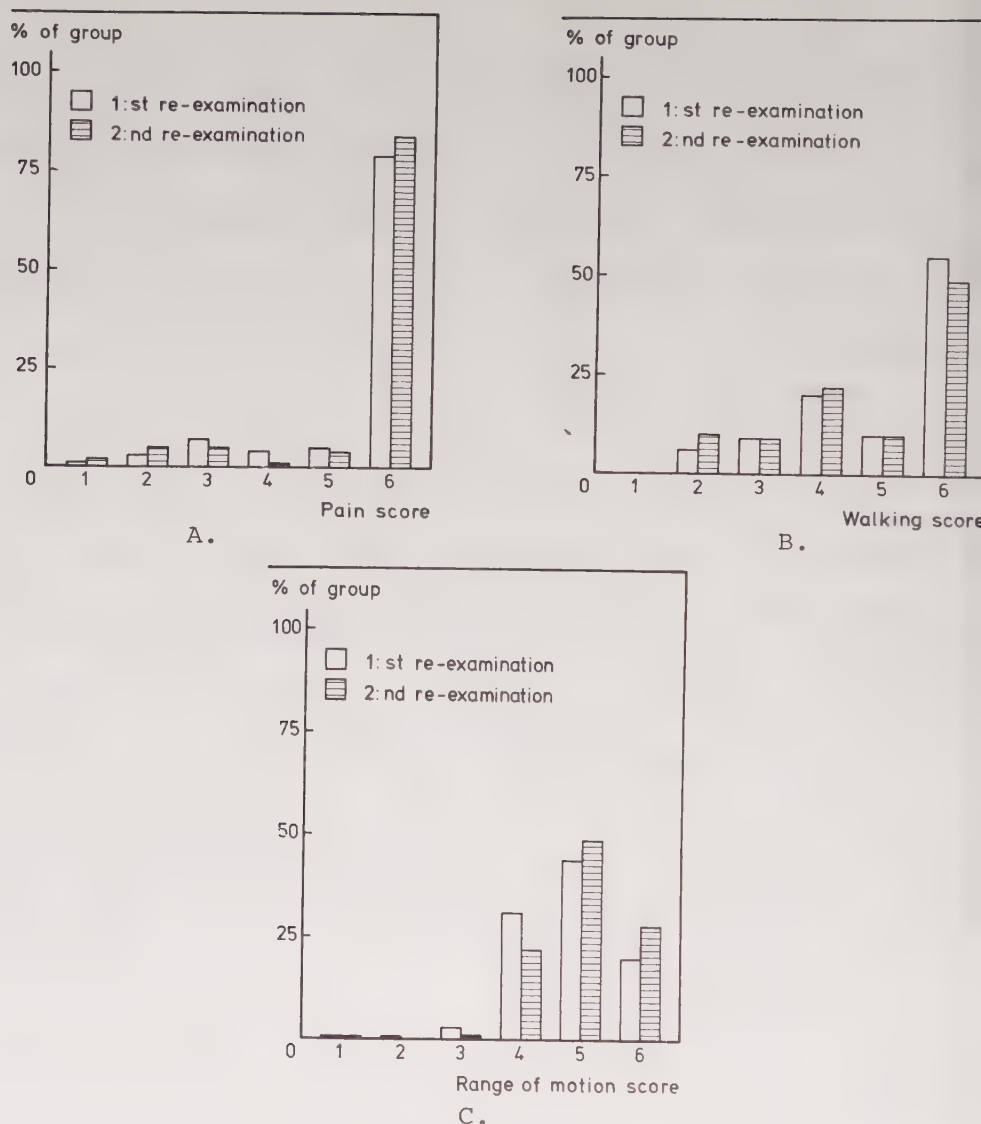


Figure I:2. Assessment of the hip function according to Merle d'Aubigné and Postel (1954) modified by Charnley (1972) in hips re-examined twice.

A. Pain. Patient categories A, B, BB and C (237 hips).

B. Function of walking. Only category A patients (69 hips).

C. Range of motion. Patient categories A, B, BB and C (237 hips).

Table I:7. Assessment of pain (P), function of walking (W) and range of motion (M) in all 13 patients with bilateral total hip arthroplasty both performed between 1968 and 1972 (category BB patients).

	Age at follow-up years	Right hip			Left hip		
		P	W	M	P	W	M
1	66	6	4	4	6	4	4
2	60	6	6	5	6	6	6
3	76	6	6	5	6	6	6
4	74	6	4	5	6	4	5
5	74	6	6	5	6	6	5
6	73	6	6	5	6	6	5
7	70	6	4	5	6	4	5
8	66	6	6	5	6	6	5
9	56	6	6	6	6	6	6
10	45	6	5	5	6	5	5
11	84	6	3	4	6	3	5
12	82	6	4	5	6	4	4
13	80	6	6	5	6	6	5
Average		6.0	5.1	4.9	6.0	5.0	5.1

First re-examination 44 per cent of the hips were completely symptomatic and 55 per cent were better than before the arthroplasty. Only three patients claimed that their symptoms were unchanged. At the second re-examination the corresponding values were 38 and 58 per cent. Four hips were unimproved and worse than before the arthroplasty. In 7 of these 9 cases there were radiographic signs of loosening of the stem prosthesis, and of these, 4 hips subsequently have been re-aced. Finally, there were 2 cases of unexplained pain at a second re-examination.

DISCUSSION

The distribution of the patients and hips with regard to diagnosis, sex and age does not differ from most of the clinical materials previously presented in the literature (Eftekhar and Stinchfield 1973, Beckenbaugh and Ilstrup 1978, Griffith et al. 1978). Remarkable in this investigation is the high rate of deep infections. This rate was reduced by antibiotic prophylaxis (Carlsson et al. 1977a). The great variation in the rate of deep infection between surgeons remains obscure.

Another remarkable phenomenon in this material is the high rate of radiographically loose femoral head prostheses. However, only a small part - about 3 per cent - of all non-infected hips have required re-operation. This figure should be compared with the rates of re-operation - 2 per cent - presented by Beckenbaugh and Ilstrup (1978) and Gruen et al. (1979).

The systemic complications are those ordinarily found in conjunction with THR (Eftekhar 1978). However, it cannot be sufficiently emphasized that the thromboembolic complications are based on clinical diagnosis in the majority of the cases and that the figures reported do not therefore represent the true incidence (Nillius and Nylander 1979).

The function results correspond with those reported by others (Eftekhar and Stinchfield 1973, Griffith et al. 1978). Since 1972 the surgical technique has been continuously improved, and there is therefore reason to believe that the complications will be less frequent and the results further improved.

SUMMARY

Three hundred and forty-two out of 351 consecutive Charnley total hip arthroplasties performed during a period of five years were reviewed once, and 233 of the non-infected hips, a second time on average 5 years postoperatively.

The initially high infection rate - 16 per cent - was reduced by antibiotic prophylaxis. The systemic complications did not differ from those described by others. Non-infectious stem loosening was observed in almost 36 per cent, but only 3 per cent required revision. Three sockets (1 per cent) were loose. The relief of pain and the functional results were rewarding and, except for some cases with stem loosening, did not deteriorate with time.

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Paper V

THIRTY-TWO NON-INFECTED TOTAL HIP REPLACEMENTS REVISED BECAUSE OF LOOSENING OF THE STEM PROSTHESIS

by

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With an increasing number of total hip replacements (THR) performed, the number of failures will also increase. Since the rate of infections has been considerably reduced essentially by means of clean air enclosures and antibiotic prophylaxis, the majority of failures today seem to be caused by mechanical factors.

Until recently no alarming reports regarding non-infected loose acetabular prostheses in metal-to-plastic arthroplasties have appeared. In 1979, however, Charnley reported an increasing number of radiographically loose sockets in patients followed for 11-15 years (Charnley 1979).

The majority of the mechanical failures following THR reported in the literature, involve the femoral component with loose and/or fractured stems (Charnley 1975, Carlsson et al. 1977, Beckenbaugh and Ilstrup 1978, Wolf 1978, Chao 1979, Gruen et al. 1979, McBeath and Foltz 1979, Pellicci et al. 1979, Wroblewski 1979, Carlsson and Gentz 1980).

The objective of the present study was to present the results of exchange operations in a series of patients with pain and signs of mechanical loosening but without infection. Also, factors with a possible influence on the loosening process will be analyzed.

PATIENTS AND METHODS

Selection of patients

Total hip replacement (THR) was introduced in the Department of Orthopedic Surgery, Malmö General Hospital in 1968, and in 1968 - 1979 the total number of primary operations performed was about 1.450. During 1970 - 1979, 132 THR were revised owing to infection, recurrent dislocation or mechanical loosening. In 15 of these cases the primary operation had been performed in other hospitals.

Thirty-two cases with roentgenological loosening of the femoral component of their THR had no clinical, laboratory or bacteriological signs of infection and it was assumed that infection had no part in the process of loosening. This assumption was in the individual cases based on the data in Table V:1 (Carlsson 1978, Kamme and Lindberg 1980).

The selected 32 cases constituted approximately 5 per cent of the THR patients with a time lag of approximately 5 years.

The whole series of radiograms of each hip was scrutinized. Loosening was defined as a radiolucent zone developing at the metal-cement interface (Figure V:1). The amount and distribution of the cement surrounding the stem prosthesis were evaluated on radiograms taken immediately after the primary operation. Cement defects were defined as an absence of cement in the whole or in part of four defined zones (Figure V:2).



Figure V:1 A (upper left)

Patient no. 25, one month following the primary Brunswik arthroplasty. Note poor proximal cement support.

Figure V:1 B (lower left)

Patient no. 25. 51 months after the primary Brunswik arthroplasty. The radiolucent zone is indicated by smaller arrows. Distally and medially a local bone resorption is indicated by larger arrows.



Figure V:1 C (above)

Patient no. 25. The same hip revised. Also, the socket has been exchanged owing to a rough sliding surface.

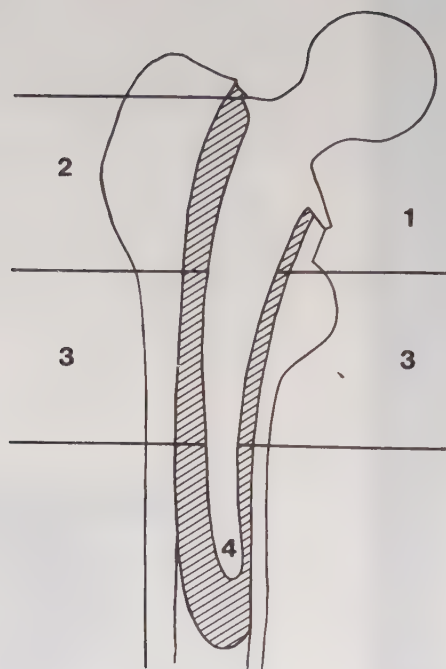


Figure V:2. The femoral zones no. 1 - 4 used for localization of cement defects.

C-reactive protein (CRP) was measured according to a precipitation method. (The antiserum was provided by Laboratories Diagnostics Company.) The normal value is $< 2 \text{ mm:s}$.

In all but two - nos. 19 and 32 - the patients had achieved total relief from pain after the primary procedure but after 6 - 100 months (30 ± 23)* the pain recurred. In patients nos. 19 and 32 there was discomfort from the beginning even if the pain first later on increased and became intolerable. All patients had pain when walking, patients nos. 7, 19 and 30, also at rest. In 24 patients the pain was located in the thigh, in 6 in thigh and groin and in 2 patients only in the groin. All patients had pain on passive motion, especially rotation.

* Average $\pm 1 \text{ SD}$

Sex, age and weight

There were 18 men and 14 women. Compared with the sex distribution in primary hip surgery during the same period, there was a significant preponderance of men ($p < 0.05$).

The average age at the primary operation had been 60 ± 9 years compared with 65 ± 10 in all patients operated upon with low friction arthroplasty between 1968 and 1972. The difference was significant ($p < 0.01$). When the sexes were compared separately, the difference was significant in both sexes ($p < 0.05$).

The body weight of these patients did not significantly deviate from that of other THR cases.

There was no tendency in the heaviest patients to have their symptoms or radiological signs of loosening earlier than the patients with lower weights.

Diagnosis and previous hip surgery

The indication for the primary THR had in 24 cases been coxarthrosis, in 3 non-infectious complications to femoral neck fractures, in 2 rheumatoid arthritis, in 2 cases necrosis following traumatic dislocation and in another case Paget's disease.

In addition to the neck fractures and the traumatic dislocation which had been combined with an acetabular fracture, two hips had previously been operated upon and with osteotomy.

Pre-exchange radiography

Pertinent data are presented in Table V:2. Twenty-five of the stem prostheses had been placed in varus position and the remaining 7 in neutral position. In all but 7 cases the tip of the prosthesis - zone no. 4 (Figure V:2) - was surrounded by cement. The cement thickness on the proximal medial side of the stem prosthesis varied between 0 and 7 mm:s. In 2 of

Table V:1. Age, sex, weight, diagnosis and investigation for infection.

No	Name	Age	Sex	Weight (kg)	ESR (mm) Value before revision in brackets	CRP (mm)	Aerobic culture	Anaerobic culture	Previous op	Diagnosis: revised hip	Diagnosis: the other hip
1	EN	61	M	93	4	0	6 neg	6 neg	no	OA	THR
2	EM	62	F	62	7	0	3 neg ^x	2 neg ^x	no	OA	THR
3	DJ	57	F	65	27 (32)	0	1 neg	1 neg	no	OA	THR
4	EE	60	F	85	21 (10)	0	3 neg	3 neg	no	OA	OA
5	AB	60	F	91	20 (18)	0	6 neg	6 neg	no	OA	normal
6	JG	37	M	69	8	0	1 neg	-	yes	neck fracture	normal
7	OC	57	F	72	17	0	3 neg	3 neg	no	OA	THR
8	TO	55	M	85	4	0	2 neg	2 neg	no	OA	OA
9	ALT	59	F	70	33 (15)	0	6 neg	5 neg 1 Bacteroides	yes	neck fracture	THR
10	AL	64	M	88	10	0	5 neg 1 staph epid	6 neg	no	OA	OA
11	KJ	65	F	74	11	0,5	6 neg	6 neg	no	OA	THR
12	EW	69	F	57	5	0	3 neg 1 staph epid	4 neg	no	OA	THR
13	SJ	63	F	92	7	-	2 neg 1 staph epid	3 neg	no	hip necrosis	normal
14	FN	62	M	70	6	-	6 neg	6 neg	no	OA	normal

15	GS	65	M	80	7	0,5	6 neg	6 neg	no	OA	normal
16	EL	55	M	56	6	-	-	-	yes	hip necrosis	normal
17	BS	47	F	70	3	0	3 neg ^x	3 neg ^x	yes	OA	OA
18	GR	73	M	81	13	0	6 neg	6 neg	no	OA	THR
19	ENo	81	M	75	23 (25)	0	3 neg	3 neg	no	OA	THR
20	IN	53	F	71	35 (23)	0,5	7 neg	6 neg	no	OA	THR
21	EF	62	F	56	83	11,0	6 neg	5 neg 1 prop acnes	no	RA	RA
22	TS	36	M	90	3	0	5 neg 1 staph epid	6 neg	yes	neck fracture	normal
23	BH	62	F	52	74	6,0	3 neg	3 neg	no	RA	RA
24	TR	56	M	71	13	0,5	6 neg	6 neg	no	Paget	THR
25	GS	60	M	80	11	1,0	6 neg	6 neg	no	OA	THR
26	SI	43	M	80	11	0,5	6 neg	6 neg	no	OA	normal
27	EA	66	M	85	1	0	6 neg	6 neg	yes	OA	OA
28	HL	72	F	63	13	0	6 neg	6 neg	no	OA	THR
29	SL	66	M	75	33 (10)	0	6 neg	6 neg	no	OA	THR
30	EP	66	M	81	6	0	6 neg	6 neg	no	OA	normal
31	SS	67	M	83	8	0	6 neg	6 neg	no	OA	THR
32	VJ	62	M	83	8	0,5	3 neg	3 neg	no	OA	THR

OA = Osteoarthritis RA = Rheumatoid arthritis

x = indicates that antibiotics were given preoperatively

Table V:2. Technical quality, pain and radiographic signs of loosening.

No	Name	Position of the stem prosthesis	Prosthesis	Cement thickness at calcar (mm)	Cement below the prosthesis (mm)	Cement defects in zone no	Lateral radio- lucent zone (mm)	Appearance of lateral zone (months)	Onset of pain (months)	Time interval pain- radiolucent zone (months)	Subsidence (mm)	Calcar resorption (mm)	Stem fracture (months)
1	EN	varus	C	1	25	1	3	13	24	11	0	4	41
2	EM	varus	C	3	45	2	4	3	10	7	0	0	30
3	DJ	neutral	C	6	50		-	-	43	-	0	4	44
4	EE	varus	C	0	10	1	6	5	21	16	5	5	65
5	AB	varus	C	2	40		2	11	100	89	0	0	100
6	JG	varus	C	5	25		8	6	30	24	5	5	
7	OC	varus	C	7	50		8	7	19	12	7	0	
8	TO	varus	C	3	65		4	5	18	13	0	0	
9	ALT	neutral	C	1	40	1	7	22	24	2	0	0	
10	AL	varus	C	2	16		3	30	56	26	2	3	
11	KJ	varus	C	1	20		13	9	31	22	10	15	
12	EW	varus	C	0	0	1	4	6	11	5	8	10	

14	FN	varus	B	2	18	1	9	32	69	37	0	8	69
15	GSu	varus	B	0	37	1 2	5	67	70	3	12	22	76
16	EL	varus	B	2	50	3	5	8	6	- 2	9	9	
17	BS	varus	B	0	0	1 2 3 4	4	11	8	- 3	0	0	
18	GR	neutral	B	0	17	1 3	3	4	7	3	0	5	
19	ENo	varus	B	0	0	1 4	5	2	2	0	4	4	
20	IN	varus	B	0	20	1 2	3	12	12	0	0	0	
21	EF	varus	B	0	7	1 2	9	2	6	4	13	23	
22	TS	neutral	B	0	0	1 3 4	4	27	23	- 4	7	18	
23	BH	neutral	B	1	90	1 2	11	13	13	0	0	8	
24	TR	varus	B	1	45	1	8	7	26	19	0	0	
25	GS	varus	B	0	20	1 2 3	6	39	53	14	13	13	
26	SI	varus	B	1	32	1 2	2	19	33	14	0	2	
27	EA	varus	B	5	18	1	9	6	24	18	16	16	
28	HL	varus	B	0	35	1	18	20	37	17	20	20	
29	SL	neutral	B	2	0	2 4	12	20	15	- 5	10	17	
30	EP	neutral	B	2	10		5	47	41	- 6	5	5	
31	SS	varus	B	0	70	1	9	22	41	19	10	10	
32	VJ	varus	S	2	0	1 2 3 4	6	34	2	-32	12	12	

B = Brunswick C = Charnley S = Stanmore

the Charnley prostheses and in 10 of the Brunswik prostheses there was complete absence of cement at the femoral calcar. In 2 of the Charnley prostheses there were cement defects in more than one zone as compared with 12 of the 19 Brunswik prostheses. Multiple cement defects were more common in Brunswik hips.

During the time period in which the primary operations of this series were undertaken, the relationship between non-infected Charnley/Brunswik hips operated on in Malmö was 288/182 whereas the relationship in the revision series was 11/19. Radiolucent zones between metal and cement at the proximal and lateral edge of the stem-prosthesis (Figure V:1) could be demonstrated in 31 cases; in patient no. 3 the trochanter was displaced and cement absent in zone no. 2. The width of the radiolucent zone was 6.5 ± 3.6 mm:s (2-18) measured just before the revision or in cases of stem fracture, on the radiograms taken before the fracture had occurred.

Fourteen of the femoral head prostheses shifted towards varus and in further 17 cases such a shift was combined with a subsidence measuring 9.2 ± 4.6 mm:s (2-20). Finally, in one case - no. 32 - there was subsidence of 12 mm:s without varus shift.

In 17 of the altogether 18 cases with subsidence of the prosthesis there was also resorption of the femoral calcar. In 6 cases the calcar was resorbed 2 - 8 mm:s without any subsidence of the prosthesis. Five Charnley prostheses and 3 Brunswik prostheses fractured between 30 and 100 months post-operatively. Four of these patients - nos. 1 - 4 - are previously described (Carlsson et al. 1977).

The exchange operation

The revisions were performed in a conventional operating theatre. With two exceptions antibiotics were not given until samples for culture had been obtained.

The types of prosthesis used at the first and second operation are presented in Table V:3.

Twenty-six of the 32 exchange operations were performed by one of the authors (ÅC), the remaining 6 by 3 different surgeons.

Twenty-eight of the revisions were performed through a lateral approach with osteotomy of the greater trochanter and 4 through a postero-lateral approach without osteotomy. The exposures were made generously. In primary surgery the hip dislocates easily but at re-operations dislocation of the hip implies mobilization of the upper femur to reduce the risk of femoral fracture and to allow extraction of the femoral head prosthesis.

The socket is always exposed for full visual inspection. In 27 cases a slot was made in the femoral cortex to ensure the removal of the cement. In 23 hips a long stem prosthesis was inserted. The extensive exploration explains why the exchange operations were time-consuming - 165 ± 36 minutes (95 - 245) and combined with more haemorrhage - 3.6 ± 1.0 litres (0.9 - 7.8). The corresponding values in primary arthroplasties were 111 ± 27 minutes and 2.2 ± 1.0 litres.

In 14 cases both the stem and the socket were exchanged: in 7, because a prosthesis with different ball diameter was chosen, in 3 (nos. 22, 25 and 28) owing to a rough sliding surface of the socket and in 4 the socket as well as the stem prosthesis were loose (nos. 15, 27, 29 and 31). After tissue samples for aerobic and anaerobic cultures had been obtained antibiotics were given intravenously. In 29 of the 32 cases gentamicin-containing cement was used.

The time interval primary operation - exchange operation was 61 ± 22 months (10 - 100).

Table V:3. Data of the primary and secondary operation, the postoperative course and the results at the re-examination.

No	Name	First prosthesis Date	Second prosthesis Date	Interval between operations (months)	Time of observ. (months)	Patient category	Function at follow up Pain Walk- Motion ing	Comment
1	EN	9/70	4/75	55	55	BB	6 6 6	
2	EM	3/73	9/75	30	50	BB	6 6 5	
3	DJ	10/72	7/76	45	46	BB	5 6 6	
4	EE	4/70	12/76	80	36	B	6 6 6	pulm. embolism
5	AB	4/70	8/78	100	15	A	6 4 6	
6	JG	2/70	1/75	59	-	A	re-exchanged	see text
7	OC	9/71	4/75	43	60	C	3 2 4	fem.fract
8	TO	3/71	5/75	50	54	B	6 6 4	
9	ALT	5/72	9/77	64	27	BB	6 4 5	
10	AL	9/71	2/78	77	26	B	6 6 5	
11	KJ	11/70	5/78	90	24	BB	5 4 5	
12	EW	11/77	5/79	18	11	BB	6 4 6	
13	SJ	5/74	4/78	47	25	C	6 3 5	loose socket
14	FN	11/72	10/78	71	14	A	6 6 4	
15	GSu	11/72	3/79	76	13	BB	6 4 6	

Follow-up examination

The results of the clinical examination after revision are presented according to Merle d'Aubigné and Postel as modified by Charnley (Merle d'Aubigné and Postel 1954, Charnley 1972, Charnley 1979). The patients were also grouped into categories A, B, BB and C (Charnley 1979). Category A patients are physically fit in all respects relating to function and without any defects other than their hip condition. Category B patients have both hips affected but are otherwise physically fit. Patients with both hips replaced by a total hip are categorized as BB. Category C is reserved for patients with conditions directly impairing their walking such as cardiac insufficiency, gonarthrosis or rheumatoid arthritis.

RESULTS

Findings at the exchange operation

All exchange operations revealed that the stem prostheses were loose - separated from the cement - whereas in the four cases with combined loosening of the socket and stem, the cement-socket interface was un-interrupted.

Post-operative course

Primary wound healing occurred in all cases. There was one case of clinically manifest but non-fatal pulmonary embolism and one case of dislocation treated with closed reduction and bed rest for 3 weeks with the hip in abduction. This hip has since then not dislocated. Patient no. 7, who suffered from a severe general osteoporosis, suddenly felt pain in her thigh one month post-operatively without previous trauma. The roentgen examination revealed a fracture of the femur at the level of the tip of the prosthesis. The fracture healed in traction. Patient no. 26 had a gram-negative sepsis during the first week but recovered rapidly on treatment with intravenous gentamicin. The same patient also had an incomplete peroneal nerve palsy. There were no signs of hip infection

and the ESR became normal.

In two patients the pain recurred and caused further revisions:

Patient no. 6

Three months following revision, the hip again became painful and the femur prosthesis which had been placed in varus position, was found to be loose. It was revised again after an 18 months delay. Afterwards, the hip was free from pain for about two years after which, again, there were signs and symptoms of loosening. At a third revision both prosthetic components could be demonstrated to be loose and were therefore exchanged. Two months post-operatively the patient went back to work. There had been no clinical signs of infection at any of the three revisions and both ESR and CRP were pre-operatively and a few months post-operatively normal. Although there was only one culture, which was negative at the first revision, the patient was classified as non-infected. At the second and third revisions there were multiple negative and no positive aerobic or anaerobic cultures.

Patient no. 16

At the first revision only the stem prosthesis was exchanged. The pain did not disappear although the stem had been replaced in a good position and with satisfactory cement support. ESR was 3 mm:s one year post-operatively. Now, at a second exchange operation the stem again was found to be loose and therefore exchanged, whereas the socket was left untouched since it appeared to be firmly attached. Three aerobic and anaerobic cultures were negative. Following this last revision the ESR did not become normal, the serum electrophoresis remained abnormal and the CRP was increased. Soon increasing radiolucent zones could be demonstrated at the bone-cement interface around both prosthetic components and owing to pain, the hip was exchanged for the third time.

The stem prosthesis could now be removed together with the surrounding cement in one piece and also the socket was loose. Staphylococcus epidermidis could be cultured in two out of six samples and enterococci in one out of six, whereas six anaerobic cultures were negative. Possibly the patient became infected during the second revision. Although the ESR became normal following the third and last revisions the patient never became completely free from pain. Gentamicin-containing cement was used at the second and third revision.

There were no wound infections, deep or superficial, after the revisions, with the exception of patient no. 16 (see above) who probably became infected during the second revision.

Re-examination

The results in the individual patients are presented in Table V:3. The patients were checked at 6-month intervals and the follow-up was 29 ± 16 months (7 - 60). Patients nos. 6 and 16 were excluded owing to secondary revisions.

In 25 of the 30 cases the hips were completely pain-free and in 4 the pain was slight and decreased with activity. In patient no. 13 the socket had changed position but the hip was still pain-free. In patient no. 7 with pain score 3 the socket had migrated centrally and the varus position in which the femoral component had been placed, increased. Radiolucent zones indicated mechanical loosening. In patient no. 3 the stem prosthesis which had been placed in varus position became loose 1 year after revision. Because of tolerable pain and excellent function, re-revision has not been performed in spite of a radiolucent zone measuring 9 mm:s. Patient no. 27 suffered pain in the thigh, probably as a result of entrapment of the lateral cutaneous nerve of the thigh. Trans-cutaneous nerve stimulation was applied with good effect on the pain in this patient.

th regard to walking, three of the four participating group A patients in the follow-up had grade 6, and one, grade 4. Out of the 15 group BB patients, seven had grade 6, one grade 5 and seven grade 4 (Table V:4).

Table V:4. Pain, walking and range of motion at re-examination.

	Patient category	- Hip score -					
		1	2	3	4	5	6
Walking	A - C			1		4	25
	A				1		3
	B				1		3
	BB				7	1	7
	C	1	3	2			1
Range of motion	A - C				10	13	7

The range of motion averaged 4.9, all 30 hips included. Except for the cases 3, 6 and 16 presented above, none of the hips had radiographic signs of stem loosening after revision. Including patient no. 16 who possibly became infected during the second exchange operation, there have been no clinical or radiographic signs of infection following the exchange operations and the ESR has always returned to the pre-operative level. In all, five exchange operations - patient nos. 3, 6, 13 and 16 - are considered to be failures.

DISCUSSION

The cases of this series conform fairly well to our previous observations on loosening hip prostheses (Carlsson and Gentz 1980) in that they were younger and more often men than the average THR-patient - also varus position and incomplete cementing were common. In addition, the Brunswik cases appear

to contribute a larger portion than the Charnley cases, and the cementing technique also seems to be more wanting in the Brunswik cases.

Just as other non-infected THR cases these patients had as a rule been relieved from pain after their primary operation but the pain recurred after, on average, 30 months and subsequently became intolerable.

The radiographic signs of loosening - radiolucent zones - in the majority of the cases preceded the onset of pain (Figure V:3).

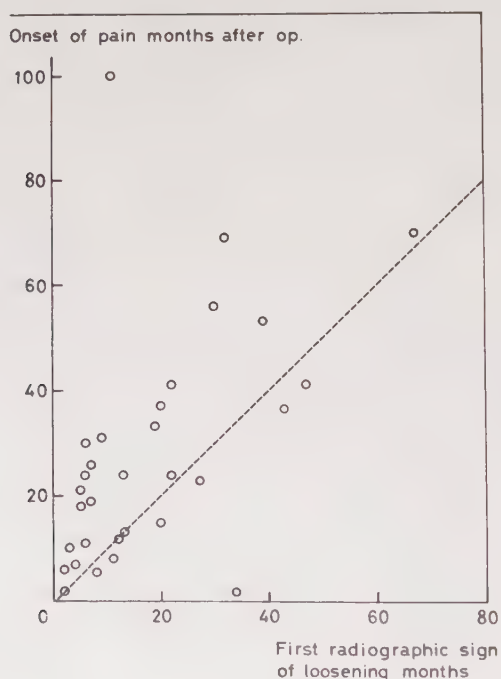


Figure V:3. Onset of pain in relation to the appearance of the radiolucent zone.

Similarly, Mc Beath and Foltz (1979) detected radiographic loosening before their patients had symptoms. These observations indicate a causal relationship and are in accordance with our previous findings that many hips with signs of loosening

may be asymptomatic, but that the risk of symptoms increases with the increasing width of the radiolucent zones (Carlsson and Gentz 1980). In the present investigation 25 out of 31 radiolucent zones measured 4 mm:s or more at the time of change operation.

In most cases it should be possible to verify or exclude septic infection from the clinical symptoms, the ESR (Reichelt and Brand 1975, Carlsson 1978) and the sequential radiographic changes (Bergström et al. 1974). However, the final answer - septic infection or not - can be provided only from cultures.

How well is the concept supported that the cases in this series were indeed not infected?

In 13 revisions there were 6 negative aerobic and anaerobic cultures. Also CRP was normal and ESR within the normal limits for age and sex.

In 2 revisions there was growth of bacteria in one out of 6 aerobic or anaerobic cultures. This growth was considered to be caused by contamination. CRP and ESR were normal.

In 6 revisions there were 3 negative aerobic and anaerobic cultures which together with normal ESR makes infection unlikely (Kamme and Lindberg 1980).

In 2 revisions there were 3 negative aerobic and anaerobic cultures but in these cases an antibiotic had been administered before culture had been obtained. In both cases CRP and ESR were normal.

In 5 revisions there were at least 3 negative aerobic and anaerobic cultures. The ESR was increased above normal limits, which in 2 cases could be explained by rheumatoid arthritis. In the three non-rheumatoid patients the CRP was normal.

f) In 4 revisions there were too few cultures but both CRP and ESR were normal.

A localized bone resorption in the femoral cortex was seen in patients nos. 10, 14, 15, 25 and 30. This phenomenon has been described both in cases with and without infection (Bergström et al. 1974, Harris et al. 1976). In our patients the radiographic changes could be explained solely on mechanical grounds.

The single positive cultures in cases nos. 9, 10, 12, 13, 21 and 22 all indicate growth of bacteria of low virulence. Kamme and Lindberg (1980) claimed that growth in 2 out of 6 per-operative aerobic and anaerobic cultures, may still be explained as contamination. It must be concluded that the diagnosis of deep infection could not be secured in any of the patients in this study, and that infection was unlikely in all 32 cases. One consequence of this assumption was that in 18 cases only the femoral component was exchanged. If any doubt should arise, it is, however, recommended that both components be exchanged so that the gentamicin-containing cement may eradicate a possibly existing infection.

In spite of the increased operating-time and the hemorrhage, the patients sustained their exchange operations well - in fact no worse than the primary operation, and with few post-operative complications. This is in contrast to the results of Hunter et al. (1979) who found that 22% of revised THR had to be excised regardless of infection or not and also in contrast to Dandy and Theodorou (1975).

Previous surgery in THR is associated with an increased risk infection (Dupont and Charnley 1972, Fitzgerald et al. 1977, Nelson 1977). With the techniques used in the present series - general prophylactic antibiotics and, in most instances, gentamicin-containing cement - only one possible infection was encountered. The risk of infection, therefore, must not preve

the exchange of a painful loosened prosthesis.

The functional results in our series are similar to those of Stekhar (1976) and Wolf (1978) but not fully comparable with those of primary operations, for example, as reported by Griffith et al. (1978). Also, again with the follow-up time in mind, it appears as if the exchanged stem prostheses remain in position. Three of the failures in this respect may be explained on technical grounds and there is no evidence that an exchanged femoral head prosthesis is less durable than one inserted at a primary operation.

Of fourteen exchanged sockets, one has loosened and another socket in a woman with severe osteoporosis has migrated medially. The bone surface encountered in secondary operations of the acetabulum is not ideal for cementation and Charnley (Charnley 1979) believes that sockets tend to be less durable for every exchange.

The Paget patient in this study had bilateral coxarthrosis and bilateral THR-operations. The exchanged prosthesis as well as the contralateral primary prosthesis have both remained intact.

As seen in Tables V:3 and 4 almost all patients became pain-free and with satisfactory walking capacity and range of motion. It should be noticed that the observation time is less than one year in three cases. In our opinion the results are encouraging. The majority of the revised patients seem to have benefited from the operation.

SUMMARY

A series of 32 total hip arthroplasties with radiographic signs of loosening were revised because of pain. Infected cases were excluded from this study on the basis of the clinical,

radiological and laboratory findings. In spite of an increased operating time and hemorrhage the complications were few. The result of the revision was in most patients a pain-free hip with good function. There was one possible post-revision infection and four additional failures. However, none of the patients become confined to wheel-chair and none ended with an excised hip.

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HANICAL FAILURE OF TOTAL HIP REPLACEMENT

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is thesis is based on the following papers:

Carlsson, Å.S.: 351 TOTAL HIP REPLACEMENTS ACCORDING TO CHARNLEY. A REVIEW OF COMPLICATIONS AND FUNCTIONAL RESULTS. Submitted for publication.

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Carlsson, Å.S., Gentz, C.F. and Lindberg, H.O.: THIRTY-TWO NON-INFECTED TOTAL HIP REPLACEMENTS REVISED BECAUSE OF LOOSENING OF THE STEM PROSTHESIS. Submitted for publication.

the following presentation these papers have been referred by their Roman numerals.

INTRODUCTION

It is not my intention to give a complete exposé of all events in the development of hip surgery that finally emerged into total hip replacement (THR). Readers particularly interested in those aspects are referred to the excellent surveys by Thompson (1966), Shands (1973) and Eftekhari (1978).

Single attempts to treat hips destroyed by disease or trauma were surgically started in the beginning of the 19th century. The development took place in five major steps: osteotomy, arthroplasty, interpositioning arthroplasty, reconstructive arthroplasty, replacement arthroplasty and total arthroplasty.

- 1 In 1826 Barton made an ankylosed hip mobile with an intertrochanteric osteotomy followed by post-operative manipulations (Barton 1827). Later in the century, the method was modified by others.
- 2 Ollier (1885) initiated an interpositioning hip arthroplasty. Several human tissues and artificial materials were being used with the intention of preventing bone overgrowth. However, ankylosis of the hip was usually the final outcome of these procedures. In 1923, Smith-Petersen implanted a glass mold, and in 1938 a mold made of a cobalt-chromium alloy. This last procedure became popular and it became obvious that the acetabulum could tolerate a foreign body (Smith-Petersen 1948).
- 3 Several types of reconstruction of the upper end of the femur were used in the beginning of the century. The Girdlestone (1945) procedure is still in use, but mainly as the last measure in failed THR.
- 4 The plastic methyl-metacrylate device introduced by the Judet and Judet (1950) became very popular and a

large number of prostheses had already been inserted when it was realized that loosening and deformation of the prosthesis were very common. During the 1950's about 50 designs were introduced with a tendency towards longer stems and metallic heads. The most prominent examples of replacement surgery are the still working designs developed by Moore (1952) and Thompson (1952). However, the indications for the use of these prostheses have changed.

- Ad 5 In 1890, Gluck implanted a knee-prosthesis made from ivory using a cement composed of colophony, pumice powder and plaster of Paris for fixation. In 1938, Wiles (Wiles 1958) operated on six hips with all stainless steel prostheses which were anchored to the bone with bolts and screws. Habousch (1953) reported on self-curing cement which was used for fixation of a vitallium prosthesis - the results were poor. McKee (1951) and McKee and Watson-Farrar (1966) presented metal-to-metal hip prosthesis. Metal-to-metal prostheses, however, disappeared from the market in the 1970s because of non-infectious loosening in a high proportion (Wilson and Scales 1970, Pattersson and Brown 1971, Wilson et al. 1972, Dandy and Theodorou 1975). Charnley had his first clinical experience with a stainless steel femoral head prosthesis and Teflon acetabular prosthesis, and in 1960 he introduced the self-curing acrylic cement (Charnley 1961). From 1962 the Teflon socket, which proved to wear rapidly, was replaced by a socket made from ultra high molecular weight polyethylene. Eighteen years later, the basic principles remain unchanged even if the materials, designs and the surgical technique have gradually been improved. In the history of orthopedic surgery few methods have survived for such a long period.

the early era of total hip replacement, (THR) technical difficulties were encountered mainly due to defect properties of the manufacturing materials or combinations of materials. This problem is, it seems, inherent in all the metal-to-metal placements (Eftekhar 1978). However, when these difficulties were overcome and the presentations of THR patients on the whole became very optimistic, complications were still reported such as dislocation of the prosthesis and dislocation or non-union of the trochanter osteotomy after the Charnley hip placement.

Subsequently, it became apparent that deep infection was a serious complication, usually with a disastrous result leading to extraction of the prosthesis. From the beginning, the reported frequencies of infection differed enormously owing to differences in the definitions and in the efforts invested in the diagnosis of infection. During this period of time "osteomyelitis" was considered to be an important cause of loosening, unrelated to infection. In time it became obvious that loosening of the prosthesis in the cement-bone interface was almost always caused by infection (Lindberg 1978). As time passed, more sophisticated methods of culturing from hips were introduced so that anaerobic infections could be detected and infections be diagnosed that were caused by micro-organisms, usually considered to be apathogenic or having a low virulence. Thus, staphylococcus epidermidis, propionibacterium species and peptococci have been demonstrated to cause a great part of delayed infections (Kamme and Lindberg 1980). Over the years, great efforts have been made to prevent infection including clean air enclosures, per-operative antibiotic prophylaxis and the addition of gentamicin to the cement (Buchholz and Gartmann 1972, Ericson et al. 1973, Charnley 1979). Even if the problem of deep infection is not solved, the rate of infection has in most centres been brought down to a tolerable level. Again, the interest has been focused on other causes of loosening of the prostheses. Whether a loosening in the bone-cement interface can be caused by other agents than

infection is not quite clear. The problem of metal allergy by no means resolved, as a cause of failure, but even if it exists, it is certainly rare (Carlsson et al. 1980).

Loosening of the prosthesis, n.b. the femoral component, owing to a separation in the metal-cement interface, was early observed and it appeared as if this separation could take place without any preceding failure of the bone-cement contact. In hips operated on with the Charnley prosthesis, a radiolucency zone between the cement and the femur prosthesis was reported by Weber and Charnley (1975), Bocco et al. (1977), Beckenbaugh and Ilstrup (1978) and Gruen et al. (1979). Charnley (1979), however, found more often signs of failure of the acetabular component than of the femoral component.

In the Department of Orthopedic Surgery in the Malmö General Hospital the original method of Charnley was introduced in 1968. At the beginning, no special precautions were taken against infection. This resulted in a very high infection rate (Carlsson et al. 1977). However, unlike in many centres the high rate of infection was recognized in that the wound of re-operated patients were cultured, also anaerobic culture being introduced at an early stage. Stepwise, the infection rate was brought down by changing various routines. The elaborate bacteriological procedures had the advantage in that the remaining cases could be classified with greater assurance as non-infected. However, a separation in the metal-cement interface was seen in many of our patients who had no signs of infection and who were, in many cases, free from symptoms. These findings - the radiolucent zones surrounding the femoral component - were referred to as mechanical loosening, unrelated to infection and with a doubtful clinical importance.

The objective of this thesis was to find the answers to the following questions:

How frequent is a separation between the metal and the cement surrounding the stem prosthesis in patients without infection?

How does this separation proceed over the years?

What is the clinical importance of this separation with regard to pain?

How does loosening relate to the technical quality of the operation?

How does loosening relate to the condition of the patient?

It is possible to relate this separation - the radiolucent zone to the bone quality prior to surgery?

How frequently is mechanical loosening followed by fracture of the stem of the prosthesis and what is the outcome of this complication?

How often is it necessary to revise prostheses with signs of loosening and what is the outcome of such revisions?

PATIENTS

The original material consisted of 351 hips in 310 patients who had been operated on with total hip replacement according to the original method of Charnley in the Department of Orthopedic Surgery, Malmö General Hospital. The patients reviewed were excluded and the patient material used for further study is presented in Figure 1. In addition to the original 351 Charnley hips, 31 hips were included in the studies IV and

V which had either been operated on elsewhere or had had a hip replacement by some method other than the Charnley procedure.

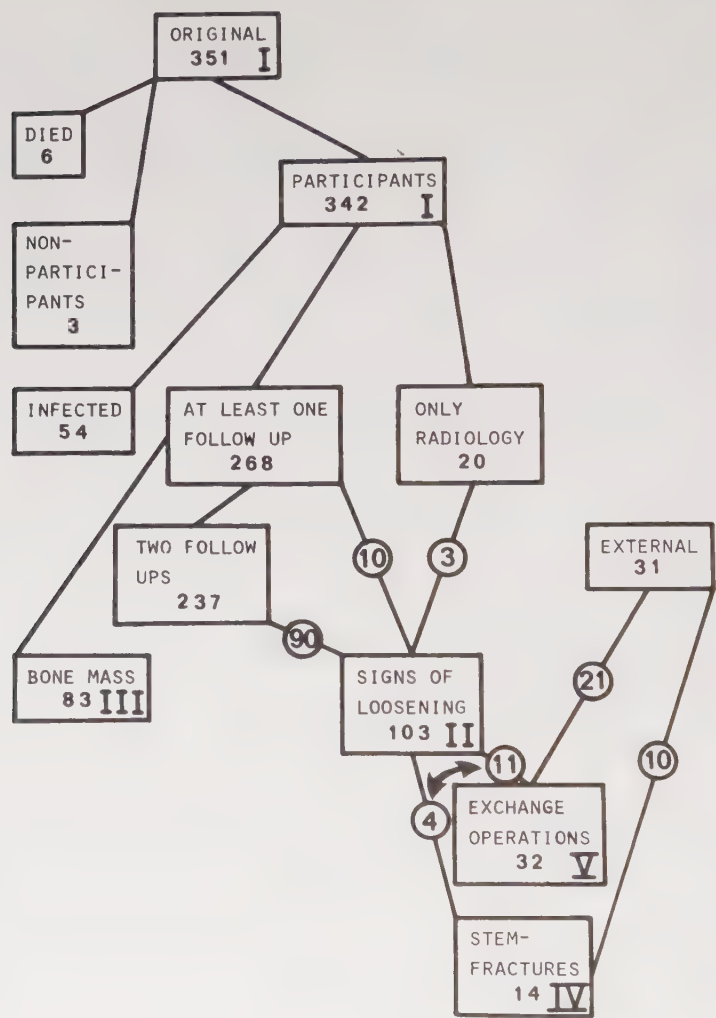


Figure 1. Flow chart of hips involved in the various studies.

SUMMARY OF PAPERS



Paper I. Three hundred and fifty-one hip replacements according to Charnley. A review of complications and functional results.

Material and methods

During a period of five years, a total of 351 hip replacements were performed according to the original method of Charnley; 342 were reviewed on at least one occasion and 237 with clinical and radiological follow-up on at least two occasions. Care was taken to reveal all infections. Radiograms were obtained with special reference to signs of infection and separation in the interface between the femoral prosthesis and the cement. Finally, standard methods were applied to classify the patients with regard to pain and function.

Results

Sixteen per cent of the hips had signs of deep infection. This group has been presented elsewhere. Thirty-six per cent of the hips had signs of separation in the metal-cement interface of the femoral component - mechanical loosening of the femoral head prosthesis. In one per cent of the hips there were signs of loosening of the socket. At the second re-examination which took place on average 6 years post-operatively, 96 per cent of the patients considered themselves improved or free from symptoms whereas 4 per cent, altogether 9 patients, were either unimproved or worse than before the operation. However, in 7 of these 9 cases there were signs of loosening of the prosthesis in the metal-cement interface and only in 2 cases did the pain remain unexplained.

Conclusions

Except for a very high frequency of recorded infections which was, to some extent, probably due to the work and interest invested in the bacteriological diagnosis, this group of THR patients did not differ with respect to the results from other series presented. The incidence of radiological signs of loosening is somewhat higher than reported in the past and this feature of THR will be further explored.

Paper II. Mechanical loosening of the head prosthesis in the Charnley total hip arthroplasty.

Material and methods

Two hundred and eighty-eight total hip replacements according to the original method of Charnley were reviewed clinically and/or radiographically. Only cases without any signs or symptoms of infection were included in this survey. Special attention was attached to the radiological appearance of the prosthesis, in particular, signs of loosening.

Results

A radiolucent zone, indicating loosening in the metal-cement-interface of the femoral component of the prosthesis was observed in 30 per cent of the hips in the first follow-up and 39 per cent at the time of the second follow-up. The rate of loosening increased rapidly in the beginning (Figure 2), whereas during the second follow-up interval loosening became less frequent.

The incidence of pain which was low in intact hips was greater in the hips with radiolucent zones; 1/4 of these hips had pain. Also, frequency of pain increased with increasing width of the radiolucent zone. Loosening was more frequent in men and in hips which had had surgery in the past. It was also more common in patients in whom a poor cementing technique had been used. Other technical variables such as the positioning of the prosthesis could not be shown to correlate with loosening. Women with loose stems had been significantly younger at the time of operation than women with intact hips whereas variables as body weight and diagnosis could not be correlated with the incidence of loosening.

Conclusions

Although there is hardly ever any separation between cement and metal to be seen in the initial post-operative radiograms of the THR hips, in the present series such a separation - a radiolucent zone - may appear rapidly within the first years

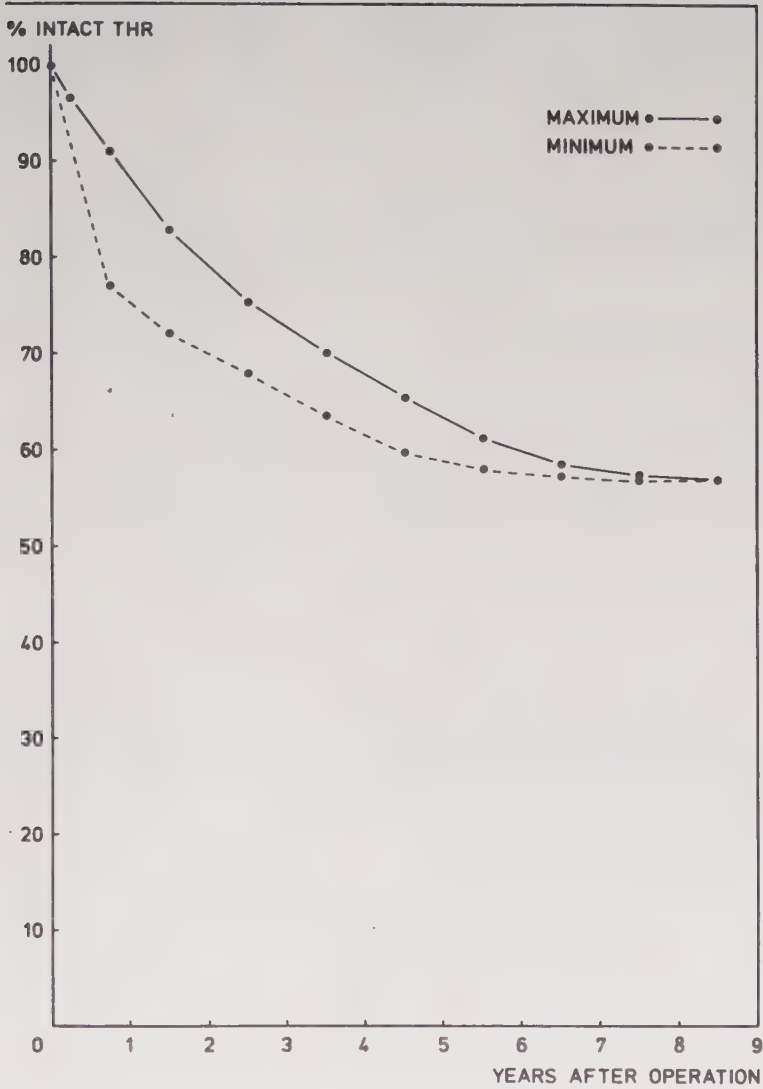


Figure 2. The rate of intact THR observed for each year of the follow-up period. The upper curve shows the actual observations. The lower curve reflects the fact that because of the time interval between radiograms, the radiolucent zone may have existed earlier. Both curves flatten out after 6 years. At this time about 60 per cent of the hips were without radiologic signs of loosening, i.e., radiolucent zone.

of the operation and, finally, be seen in almost 40 per cent of the cases. From about 6 years on there appears to be no further progress. Although most of these patients are unaware of the loosening, some indeed with time developed pain and dysfunction which in some cases even caused an exchange operation. The reason for loosening is obscure. In the present study the range of positioning of the prosthesis was probably not sufficiently wide to provide for comparisons - in most instances the technical quality of the operation was fairly good in this respect. However, poor cementing with poor support at the calcar level and an unsupported distal end of the prosthesis was so closely related to loosening as to suggest a causative relationship. Men and young women appeared to run a higher risk of loosening, otherwise the vital statistics of the patients including their diagnosis and body weight appeared to be of little importance.

Paper III. The relationship of bone mass and loosening of the femur component in total hip replacement.

Material and methods

Included in the study were 83 patients operated on with THR because of primary coxarthrosis. In 23 of the cases there was evidence of mechanical loosening between the cement and the metal stem of the femoral component appearing as a radiolucent zone. In all patients the pre-operative radiogram of the hip was evaluated with regard to the thickness of the femoral cortex and the trabecular pattern of the upper end of the femur (the method of Singh).

Results

There was no difference in the pre-operative appearance of those hips that were to go on to loosening and those that remained intact.

Conclusions

The hypothesis that the quality of the bone surrounding the

metal-cement complex implanted in the upper end of the femur could be of importance for loosening was not supported by this study. A previously observed increase in bone mass in conjunction with coxarthrosis was confirmed.

Paper IV. Fracture of the femoral head prosthesis in total hip replacement according to Charnley.

Material and methods

Included in the study were 14 patients with fracture of the stem of the hip component of the Charnley hip prosthesis. These 14 cases were drawn from a total of over 2.000 hip operations suggesting an incidence of 0.7 per cent for this particular complication.

Results

The stem fracture was always preceded by loosening - separation in the metal-cement interface of the femoral component. It became obvious after, on average, 45 months after the operation. In half of the cases, however, the stem fracture, which was difficult to see, had been overlooked in one radiographic examination thus delaying the diagnosis. In two aspects the patients with fractured stems differed from other patients with signs of loosening in that they were heavier and more often had had bilateral surgery.

Conclusions

This complication, stem fracture, is very rare, seeing the high frequency of radiological signs of loosening. It can be easily overlooked in the beginning. Since the condition is comparatively rare, in spite of the fact that loose prostheses are comparatively common, it is possible that a defect of the metal of the stem is a contributing factor.

Paper V. Thirty-two non-infected total hip replacements revised because of loosening of the stem prosthesis.

Material and methods

This series consists of 32 hips operated on with total hip replacement and with signs of mechanical loosening of the femur component but without evidence of infection. Because of pain, all 32 hips were operated on with exchange of the prosthesis. In all patients, a direct replacement was performed, removing and replacing the loose femur component; in 14 instances, the acetabular socket was also replaced, 4 of the latter being loose. In most instances, 29 cases, gentamicin-containing cement was used to attach the new prosthesis and in all cases per-operative antibiotics were used.

Results

The replacement operation was successful in 28 cases which needed no further surgery and were relieved from pain. Another hip could be rescued by another re-operation, leaving 4 with poor results - 1 patient died without further attempts at treatment, 1 patient had a loose socket, 1 patient a loose stem prosthesis and, finally, in 1 patient both the socket and the stem became loose. Except that the revision operation was somewhat more time-consuming and associated with more hemorrhage than a primary operation, no major technical difficulties were encountered. The successfully revised cases had a function comparable with that of successful primary surgery.

Conclusions

In patients with mechanical loosening of the femoral component of a hip prosthesis, replacement can be carried out and be successful in 80 - 90 per cent of the cases. Those patients who had to be operated on did not, in most respects, differ from other patients with signs of loosening except that the width of the zone of separation between metal and cement was much wider than the average.

GENERAL DISCUSSION

Patients

The distribution of patients with regard to age, sex and diagnosis is comparable with that of most other materials of unselected patients presented from the same period (Beckenbaugh and Ilstrup 1978 and others). The female preponderance is in this investigation about 1.5:1 as compared with 1:1 - 3.5:1 in previously presented data (Patterson and Brown 1972, Charnley and Cúpic, 1973, Beckenbaugh and Ilstrup 1978). Since primary coxarthrosis is the most common diagnosis in most series, and since this diagnosis is about equally common in men and women (Danielsson 1964), the preponderance of women is remarkable. There is no explanation for this finding.

It was a fortunate circumstance that attention was directed towards infection. The efforts invested in diagnosis and recording of this complication were valuable requisites for our studies on mechanical failure. Also, the easy and mutual patient-surgeon access provided serial observations in a group of patients in whom the post-operative cause was not disturbed by infection.

Surgical technique 1968 - 1972

During the period 1968 - 1972 the original method and approach of Charnley were used. However, before 1973 we were not aware of the importance of avoiding varus position and of solid cement support of the femoral component. Also, the removal of all cancellous bone was not routine practice, particularly not at the calcar level, nor even in cases with poor cancellous bone quality. Bone cement containing contrast was used in all cases, which is a prerequisite for radiological analyses.

Infections

There are several reasons why the patients classified as non-infected in this study have really been free from deep infection:

- A. The patients were almost all from the city of Malmö with easy access to their orthopedic surgeon as well as to the Department. Therefore most complaints, and certainly severe symptoms such as are seen in conjunction with deep infection will be on record.
- B. Complete follow-up.
- C. Vigorous bacteriologists.
- D. Infections continuously recorded.
- E. Consequent pre- and post-operative ESR-controls.
- F. High recorded infection rate.

Nevertheless, absolute criteria of infection or not could not be obtained on patients other than those who had required re-operation.

How to define loosening of a cemented femoral stem prosthesis (II).

The study is confined to primary loosening at the cement-metal interface. The same phenomenon can be secondary to loosening in the bone-cement interface. All such cases, however, namely those with infection, were excluded from this study. The following basic criteria may be applied:

- A. Radiographic change of the position of the prosthesis between two subsequent examinations.
- B. Change of the position of the femoral component, in this

study always a varus shift and/or a subsidence of the prosthesis - in both instances resulting in a proximal-lateral radiolucent zone between metal and cement.

- C. A crack in the distal part of the cement (Weber and Charnley 1975) or a fracture of the metallic stem.
- D. Gross visual inspection and palpation in conjunction with revision surgery or autopsy.

Symptoms of loosening (II, IV, V).

Loosening as defined by any of the four criteria described above, may or may not be symptomatic. Moreland (1980) claimed that there is a poor relationship between loosening and pain, and Ling (1980) found that only one out of 18 patients with subsided femoral head prostheses had slight pain. Also, DeSmet et al. (1978) found that 15 out of 19 patients with total hip replacements with a radiolucent zone were asymptomatic. Weber and Charnley (1975) observed that "a slight subsidence of the prosthesis in the cement bed appears to result in a new and final position of stability". In contrast, Beckenbaugh and Ilstrup (1978) found significantly poorer results in patients with signs of loosening. The latter attitude that signs of loosening represent a risk of clinical failure, is supported by the present study (II) in that hips with loosening were more often painful, particularly those hips with wide radiolucent zones.

The causal relationship between radiolucent zones and pain is supported by the fact that this sign preceded the onset of pain in the majority of the 32 revised cases (V). A similar relationship was observed by McBeath and Foltz (1979).

Rate of loosening (II)

The reported rate of loosening of the femur stem prosthesis within the cement bed varies between 0 and 24 per cent (Bocco et al. 1977, Beckenbaugh and Ilstrup 1978). In the present

investigation it was observed in about 36 per cent of the hips. We have been able to demonstrate that the loosening usually takes place within the first post-operative years and that a steady state is attained after 5 - 6 years. This schedule, of course, may be limited to the Charnley prosthesis and to the surgical technique of our Department but the pattern should also be similar under other conditions.

With the rate of loosening and the need for re-operation because of loosening observed in this study, no more than every 20th hip should require secondary surgery for this reason. However, we have no way of knowing whether or not a second wave of mechanical failures will hit our prostheses, now predominantly involving the acetabular component (Charnley 1979).

Causes of loosening (II, III, IV, V)

Many causes of loosening have been suggested. A preponderance for men is a constant finding in the literature (Charnley 1975, Chao 1979, Pellicci et al. 1979, McBeath and Foltz 1979) whereas the importance of age and body weight is less clear. Physical activity is another factor of probable importance but this variable cannot readily be accounted for.

From the technical point of view it seems fairly obvious that varus position of the femur prosthesis should be avoided, that the cancellous bone should be removed and that the femoral marrow cavity should be filled with cement to avoid loosening. In our studies (II, IV, V), cement defects were usually found around the prosthesis in cases with loosening or fracture. So far, no short or long-term investigations of THR, operated on with plugging of the femoral canal and the closed cavity technique, have been presented. Previous surgery also seems to predispose for subsequent loosening (McBeath and Foltz 1979).

In the present study, it was demonstrated that male sex, poor cementing and previous surgery predisposed for stem loosening.

The importance of the varus position was non-significant, possibly because of a rather small variation.

Inferior bone quality could theoretically predispose for subsequent loosening of the femoral stem prosthesis but this hypothesis which was proposed by Amstutz et al. (1976) could not be confirmed from our comparisons of the bone mass in coxarthrosis THR-patients with and without femoral stem loosening (III).

Fracture of the femoral prosthesis is in our opinion only an ultimate fate of a metallic stem already loose in its proximal end and fixed distally. Once it is loose the forces acting on the prosthesis are increased significantly (Amstutz and Markolf 1974, Andriacchi et al. 1976) and the repeated loading results in a metal fatigue fracture. In some of our cases it was noticed that the prostheses were twisted and the conclusion drawn from this finding was that not only vertical forces are of importance. This finding was to be verified by Wroblewski (1979), who also found the fractured prostheses to be twisted and that the fracture started at the corner of the "flat back" of the prosthesis. The reason is that at "heel strike" the hip is loaded in about 20° - 30° of flexion. Thus, the load on the stem prosthesis is also directed downwards and backwards, leading to bending and axial torque (Chao 1979, Wroblewski 1979).

The rate of fracture of the Charnley femoral stem is between 0.2 - 0.7 per cent but it should be realized that until now no fractured "round back" femoral stems have been reported (Charnley 1975, Carlsson et al. 1977 (IV), Wroblewski 1979, 1980).

Rostoker et al. (1978) reported metallic defects in almost all of 34 fractured stems, and emphasized that crack-like flaws or stress concentrations including surface roughness, scratches and pits may initiate fatigue cracks. The fact that stem fractures do occur at all but are still very rare indicates

that material defects of some kind must contribute.

Revision after loosening (V)

Revision may be necessary in hips with bone resorption secondary to loosening in order to preserve bone stock. However, pain is the most common cause of surgery in cases of loose femoral head prosthesis and pain was the cause of operation in all our cases.

The results were therefore rewarding in the sense that pain was relieved in most cases. The complications and failures were few. Even if more than one procedure has been or will be required in one tenth of the patients, the potential disaster could almost always be prevented.

GENERAL SUMMARY AND CONCLUSIONS

On the basis of about 380 total hip replacements, the rate of loosening of the stem prosthesis, the symptoms of loosening, the rate of fracture of the metallic stem and the outcome of revision in cases of non-infectious stem loosening were studied. An attempt was also made to evaluate factors causing loosening, including the pre-operative quality of the bone.

The following conclusions could be drawn:

1. Loosening of the stem prosthesis - a radiolucent zone - was observed in 36 per cent.
2. Loosening was most commonly observed during the first post-operative years; a steady state was reached after 5 - 6 years.
3. The radiolucent zone - the loosening - preceded the pain which was present in about 25 per cent of the cases. Moreover, with increasing width of the radiolucent zone,

the fraction of painful hips increased. In hips with a zone of 4 mm or more, 50 per cent were painful.

4. Defects in the cement support were found to promote loosening whereas varus malposition, although common in loosened hips requiring revisions, could not be demonstrated to contribute significantly.
5. Male sex, previous hip surgery and, in women, young age, were correlated to loosening whereas diagnosis, body weight and, in men, age, was not. With respect to stem fracture, heavy male patients with bilateral THR make a risk group.
6. Loosening was not correlated with the pre-operative bone-quality.
7. The frequency of stem-fracture was about 0.7 per cent.
8. Three per cent of all non-infected hips and 8 per cent of the loosened stems required revision which in most cases relieved the pain and resulted in a good walking capacity and range of motion.

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Thesis
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